K091139

MAY - 5 2009

4. Summary of Safety and Effectiveness

Submitted by:	CONMED Electrosurgery Division 14603 East Fremont Avenue Centennial, CO 80112 USA Telephone: 303-269-8296 Facsimile: 303-699-9854
Contact Person:	Damaris Velez
Date Prepared:	February 12, 2009
Proprietary Name:	CONMED® Aer Defense™ Smoke Evacuator
Common Name:	Electrosurgical Surgical Smoke Evacuator
Classification Name:	Apparatus, Exhaust, Surgical FYD
Predicate Device:	This product is similar in design, composition, and function to the Porta Plumesafe™ 601 Smoke Evacuation System, K924732 and the Smoke Evacuation section of the ConMed Integrated Service Manager SM40SE, K053464.

Technological Characteristics

Smoke Evacuator:

The CONMED Aer Defense™ Smoke Evacuator has been designed with a high suction, high flow rate, two-stage thru flow vacuum motor. Its motor is used to draw the surgical smoke from the surgical site, through the vacuum tubing and into the CONMED Aer Defense™ Smoke Evacuator's filter where the surgical smoke is processed by a series of filtration stages. A single disposable filter is used to simplify the installation and removal during filter changes.

Filter:

The filter for the Aer Defense™ Smoke Evacuator, like the filters for the predicate devices, is a replaceable self-contained filter that is completely enclosed to help protect the health care personnel from potential contamination during filter changes. The FilterOne™ is an Ultra Low Penetration Air (ULPA) grade with carbon filter that has a filter efficiency of 99.9995% for particle sizes of 0.12µm or greater. These characteristics are identical to the predicate filters.

The filter life for the FilterOne™ is based on the flow rate through the filter and is 35 hrs in Lap Mode, and 10 hrs at maximum flow in Normal Mode. The filter life for the

predicate devices is based on time of use and is 8 hrs maximum. Bench testing has shown that the filter life for the Aer Defense™ Smoke Evacuator is substantially equivalent to the predicate filters based on bench testing.

Suction Flow Rate:

The maximum suction flow rate for the Aer Defense™ Smoke Evacuator ranges from a maximum 20 LPM in Laparoscopic Mode to 25 CFM in Normal Mode and is substantially equivalent to the flow range of 20 LPM in Normal Mode and 34 CFM in Boost Mode for the predicate devices, K924732 and K053464.

Performance Characteristics:

Performance Testing: Design Verification & Validation bench testing was designed and conducted to show that the Aer Defense™ Smoke Evacuator operates as safe and effective as the predicate devices, K924732 and K053464.

Electrical Verification testing showed that the Aer Defense™ Smoke Evacuator met its operational mode and electrical design requirements as specified in the test protocol. Test results indicate that the Aer Defense™ Smoke Evacuator is substantially equivalent to the predicate devices, K924732 and K053464.

Mechanical Verification testing has shown that the Aer Defense™ Smoke Evacuator has met its mechanical design requirements as specified in the protocol. Test results indicate that the Aer Defense™ Smoke Evacuator is substantially equivalent to the predicate devices, K924732 and K053464.

Software Verification testing has shown that the Aer Defense™ Smoke Evacuator has met the operational mode and software design requirements as specified in the protocol. Test results indicate that the Aer Defense™ Smoke Evacuator is substantially equivalent to the predicate devices, K924732 and K053464.

Validation testing has shown that the Aer Defense™ Smoke Evacuator has met its operational mode and validation requirements. Test results indicate that the Aer Defense™ Smoke Evacuator is substantially equivalent to the predicate devices, K924732 and K053464.

These acceptable test results for the non-clinical bench testing indicate that the Aer Defense™ Smoke Evacuator operation is substantially equivalent to the predicate devices, K924732 and K053464.

Electrical Safety:

Electrical Safety testing that was conducted for the Aer Defense™ Smoke Evacuator was done according to IEC 60601-1-1, IEC 60601-1-2, and UL 60601-1. This testing

indicates that the electrical safety for the Aer Defense™ Smoke Evacuator is substantially equivalent to the predicate devices, K924732 and K053464.

Modes of Operation:

Normal Mode – Normal mode is the default activation mode. The smoke evacuator will run in this mode when none of the available modes have been selected and illuminated on the control panel (Laparoscopic, Continuous, Automatic, or Footswitch). While in Normal Mode, the smoke evacuator will start suction upon activation from an ESU. The Normal Mode is substantially equivalent to the Normal Mode and Boost Mode in predicate devices, K924732 and K053464.

Laparoscopic Mode – This mode is designed to provide a low flow suction control range for use in minimally invasive procedures. Laparoscopic mode is controlled by Normal, ConMed ESU Automatic, Footswitch, or Continuous activation modes. The Laparoscopic Mode is substantially equivalent to the Laparoscopic Mode and the Normal Mode in predicate devices K053464 and K924732 respectively.

Footswitch Mode – This mode starts suction upon activation of the Pneumatic Footswitch only. The smoke evacuator can be turned on or off by depressing the footswitch once to turn suction on and once again to turn suction off. This mode functions the same as the Footswitch Mode for the predicate devices, K924732 and K053464.

Continuous Activation Mode – This mode runs the smoke evacuator at the selected power level continuously, without activation of the Handpiece, until the mode has been deselected, another mode is selected, or the unit is turned off. This operating mode is not available in the predicate devices.

Electrical and Software Verification bench testing has shown this mode to be as safe and effective as the normal operation of the device and is substantially equivalent to the predicate devices, K924732 and K053464.

ConMed ESU Automatic Mode – This mode starts suction upon Handpiece activation from either a ConMed System 5000 or System 2450 ESU. The smoke evacuator will also employ automatic adjustments of the flow level based on the ConMed ESU power usage. This operating mode is not available in the predicate devices.

Electrical and Software Verification bench testing has shown this mode to be as safe and effective as the normal operation of the device and is substantially equivalent to the predicate devices, K924732 and K053464.

Integrated Operating Room Interface Mode – This mode allows the smoke evacuator front panel controls to be set through the devices serial port by an integrated operating room control center. This operating mode is not available in the predicate devices.

Electrical and Software Verification bench testing has shown this mode to be as safe and effective as the normal operation of the device and is substantially equivalent to the predicate devices, K924732 and K053464.

Biocompatibility:

The CONMED® Aer Defense™ Smoke Evacuator and the predicate devices do not contact the patient and are substantially equivalent regarding biocompatibility.

Indication for Use:

The CONMED® Aer Defense™ Smoke Evacuator is designed to remove smoke, aerosols and mitigate odors produced by surgical smoke during electrosurgical procedures. This indication is substantially equivalent to the indications of the predicate devices, K924732 and K053464.

Summary:

The Electrical, Mechanical, Software, and Safety testing indicate that the CONMED® Aer Defense™ Smoke Evacuator is substantially equivalent to the predicate devices identified in K924732 and K053464.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2009

Underwriters Laboratories, Incorporated
C/O Mr. Jeff D. Rongero
Responsible Third Party Official
Conmed Corporation
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

Re: K091139
Trade/Device Name: Conmed Aer Defense Smoke Evacuator
Regulation Number: 21 CFR 878.5070
Regulatory Class: II
Product Code: FYD
Dated: April 17, 2009
Received: April 20, 2009

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. **Indications for Use**

510(k) Number (if known): K091139

Device Name: CONMED® Aer Defense™ Smoke Evacuator

Indications for Use:

The CONMED Aer Defense™ Smoke Evacuator is designed to remove smoke, aerosols and mitigate odors produced by surgical smoke during electrosurgical procedures.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091139